DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

WARNING LETTER

July 6, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert E. Hinckley, President/CEO
Bimeda Animal Health Inc.
460 NW Parkway
Riverside, Missouri 64150

Ref. #KAN-2000-020

Dear Mr. Hinckley:

Investigation of your veterinary sales facility by the Food and Drug Administration (FDA) revealed improper sales of veterinary prescription drugs. Sales were made without a valid veterinarian/client/patient relationship (VCPR) or to firms who are not lawfully engaged in distributing prescription drugs. Such sales are a serious violation of Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act (the Act).

A valid veterinarian/client/patient relationship has been defined in Title 21 of the Code of Federal Regulations [21 CFR 530(i)] as one in which:

1. A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;

2. There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and

3. The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

You are selling prescription veterinary drugs such as Gentamicin Sulfate Solution, Cyanocobalamin Injection Vitamin B-12, and Hypertonic Saline Solution, which are misbranded within the meaning of Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act [the Act] in that they do not have adequate directions for use.

"Adequate directions for use" according to Title 21 of the Code of Federal Regulations (CFR) 201.5 means adequate directions under which the layman can use a drug safely and for the purposes for which is was intended. Prescription drugs, according to Section 503 of the Act, are those which are not safe for animal use because of their toxicity or potentiality for harmful effect except under the professional supervision of a licensed veterinarian. They do not bear adequate directions for use by laypersons because they cannot be written.

Within a valid VCPR, prescription animal drugs are exempt from adequate directions for lay use; the veterinarian's supervision can be substituted for the legal requirement that drugs be labeled with adequate directions for use. Without supervision, prescription drugs are misbranded because they lack adequate directions for the layperson to use them safely. You have sold drugs to [redacted] without a veterinarian's supervision. Also, prescription veterinary drugs are exempt from the statutory requirements for adequate directions for lay use only when they are in the possession of a person regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of drugs that are to be used by or on the prescription or other order of a licensed veterinarian. You sold drugs to [redacted] a firm that is not lawfully engaged because they distribute drugs to laypersons without a valid VCPR.

You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure and/or injunction.

This is not intended to be an all-inclusive list of violations that may be present in your firm. You, as the President/CEO of this firm have a responsibility to insure that all drugs distributed by your firm comply with all legal and regulatory requirements.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step to prevent the recurrence of similar violations. Also include copies of any appropriate documentation demonstrating that corrections have been made.

If you have further questions or concerns, you should reply directly to Monica R. Maxwell, Compliance Officer, at the above address.

Sincerely yours,

Charles W. Sedgwick
District Director